

REMARKS/ARGUMENTS

The rejections presented in the Office Action dated March 8, 2007 (hereinafter Office Action) have been considered. Claims 1-62 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1, 15-17, and 21-27 are amended. Support for the amendments to independent claims 1 and 21 can be found in the Specification on page 20, lines 7-17; page 22, lines 1-7; and at Col. 6, Lines 17-19 of U.S. Patent No. 6,285,907, which is incorporated by reference by the Specification at Page 13; among other locations. The amendments to dependent claims 15-17 and 22-27 carry through the amendments to independent claims 1 and 21, respectively. Accordingly, no new matter has been added.

The Applicant respectfully submits that the present responsive amendment should be entered and considered because the Examiner has previously searched and considered the subject matter of the claims, as amended. For example, claim 1 originally recited "energy delivery circuitry capable of delivering a plurality of cardiac therapies comprising at least a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy." Therefore, systems for delivering at least a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy have already been searched.

The amendments respond to the rejection by enhancing the clarity of the claims, not by adding subject matter necessitated by the cited prior art. Hence, the Applicant submits that the present responsive amendment does not necessitate a new search or further consideration that would present an undue burden to the Examiner.

Claims 1-5, 8, 13-14, 19-25, 28-29, 33-41, 44, 47-54, 57, and 60-62 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Publication No. 2002/0035376 by *Bardy et al.* (hereinafter "*Bardy* '376"). Claims 1-5, 8, 13-25, 28-41, 44, 47-54, 57, and 60-62 stand rejected under 35 U.S.C. §102(a) as being anticipated by U.S. Publication No. 2002/0091414 by *Bardy* (hereinafter "*Bardy* '414").

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either

expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

The Applicant's independent claims 1 and 21 each recite, among other features, some variation of therapy instructions stored in the energy delivery circuitry, the therapy instructions executable to direct delivery of the tachycardia therapy, the bradycardia therapy, and the asystole prevention therapy.

An anticipatory reference of independent claims 1 and 21 must disclose a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy. The Applicant respectfully submits that *Bardy* '376 and *Bardy* '414 each fail to teach at least an asystole prevention therapy. Moreover, neither *Bardy* '376 nor *Bardy* '414 even describe an asystolic condition.

As such, neither *Bardy* '376 nor *Bardy* '414 teach therapy instructions stored in energy delivery circuitry, the therapy instructions executable to direct delivery of the tachycardia therapy, the bradycardia therapy, and the asystole prevention therapy, as recited in independent claims 1 and 21.

Therefore, the Applicant respectfully submits that neither *Bardy* '376 nor *Bardy* '414 teach each and every element and limitation of independent claims 1 and 21, and therefore fails to anticipate these claims.

The Applicant's independent claim 37 recites, among other features, delivering one of a plurality of available cardiac therapies to treat the detected cardiac condition, the plurality of cardiac therapies comprising at least a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy. The Applicant's independent claim 50 recites, among other features, means for delivering one of a plurality of cardiac therapies to treat the detected cardiac condition, the plurality of cardiac therapies comprising at least a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy, all of which can be delivered by the system.

As discussed above, neither *Bardy* '376 nor *Bardy* '414 describe an asystole prevention therapy or an asystolic condition.

In addressing the rejection of independent claims 37 and 50, the Examiner repeatedly recites some variation of delivery *one of* a plurality of cardiac therapies comprising at least a tachycardia, a bradycardia therapy, and an asystole prevention therapy. (See Office Action, Pages 3, 4, and 7; emphasis original). The Applicant respectfully submits that anticipation of either of independent claims 37 and 50 requires more than a showing of delivering one of the above recited therapies.

For example, anticipation of independent claim 37 requires a teaching that an asystole prevention therapy be available for delivery (“a plurality of available cardiac therapies to treat the detected cardiac condition, the plurality of cardiac therapies comprising at least a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy” – claim 37).

Furthermore, anticipation of independent claim 50 requires a teaching of means for delivering an asystole prevention therapy.

Considering that neither *Bardy* '376 nor *Bardy* '414 describe an asystole therapy or an asystolic condition, there is no support within these references for an asystole prevention therapy or that such a therapy is available to be delivered. The Applicant respectfully submits that speculation about what *Bardy* '376 and *Bardy* '414 may be capable of, if configured in a way not taught by either reference, is not a substitute for identifying a teaching to properly support an anticipation rejection.

As such, the Applicant respectfully submits that both *Bardy* '376 and *Bardy* '414 fail to teach each and every element and limitation of independent claims 37 and 50, and therefore cannot sustain an anticipation rejection of these claims.

The Applicant's dependent claim 15 recites wherein the asystole prevention therapy comprises delivery of pacing pulses at a rate varying between about 2 and about 40 pulses per minute.

In addressing dependent claim 15, the Office Action identifies paragraph [0078] of *Bardy* '414, the paragraph stating that “the implantable cardioverter-defibrillator employs

anti-bradycardia pacing at rates of approximately 20 to approximately 120 stimuli/minute.” (Page 8). The Applicant respectfully submits that *Bardy’s* ‘414 anti-bradycardia pacing therapy does not vary a pacing rate between about 2 and 40 pulses per minute. Merely because *Bardy* ‘414 discloses that an anti-bradycardia therapy may pace below 40 pulses per minute does not constitute a teaching of delivering an asystole prevention therapy by varying a pacing rate between about 2 and about 40 pulses per minute. As such, *Bardy* ‘414 does not teach all limitations of dependent claim 15.

The Applicant’s dependent claims 16 and 30 each recite some variation of wherein the asystole prevention therapy comprises delivery of pacing pulses at a rate insufficient to restore full patient consciousness.

In addressing dependent claims 16 and 30, the Office Action identifies the above quoted portion of *Bardy’s* ‘414 paragraph [0078] and states that “in the lower end of the range near 20 stimuli per minute, consciousness would not be restored.” The Applicant respectfully submits that *Bardy* ‘414 discloses anti-bradycardia therapy and that there is nothing in *Bardy* ‘414 that teaches that *Bardy* ‘414 discloses that the anti-bradycardia therapy regime delivers therapy such that full patient consciousness is not restored. Merely because it is within the realm of possibilities that a patient receiving *Bardy’s* ‘414 anti-bradycardia therapy could lose full consciousness, such an un-contemplated possibility does not then mean that *Bardy’s* ‘414 anti-bradycardia therapy constitutes a teaching of an asystole prevention therapy comprising delivery of pacing pulses at a rate insufficient to restore full patient consciousness. As such, *Bardy* ‘414 does not teach all limitations of dependent claims 16 or 30.

The Applicant’s dependent claims 17 and 31 each recite same variation of wherein the asystole prevention therapy comprises delivery of pacing pulses at a rate lower than a pacing rate associated with the bradycardia therapy.

In addressing dependent claims 17 and 31, the Office Action identifies *Bardy’s* ‘414 anti-bradycardia pacing therapy as described in paragraph [0078]. (Page 8). The Applicant respectfully submits that *Bardy’s* ‘414 referenced anti-bradycardia therapy is not associated with a delivery of pacing pulses at a lower rate than a pacing rate associated with

bradycardia therapy. The rejection appears to ignore that *Bardy's* '414 referenced anti-bradycardia therapy is a bradycardia therapy. As such, *Bardy* '414 does not teach all limitations of dependent claims 17 or 31.

Dependent claim 2-5, 8, 13-20, 22-25, 28-36, 38-41, 44, 47-49, 51-54, 57, and 60-62, which are dependent from independent claims 1, 21, 37, and 50, respectively, were also rejected under 35 U.S.C. §102(a) and (b) as being unpatentable over *Bardy* '414 and *Bardy* '376, respectively. While the Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 21, 37, and 50. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 2-5, 8, 13-20, 22-25, 28-36, 38-41, 44, 47-49, 51-54, 57, and 60-62 are also not anticipated by *Bardy* '414 nor *Bardy* '376.

For at least these reasons, the Applicant respectfully submits that the rejection of claims 1-5, 8, 13-25, 28-41, 44, 47-54, 57, and 60-62 as being anticipated by *Bardy* '414 or *Bardy* '376 is not sustainable.

Claims 6, 26, 42, and 55 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Bardy* '376 as applied to claims 1, 21, 37, and 50 and further in view of U.S. Patent No. 4,562,841 to *Brockway et al.* (hereinafter "*Brockway*"). Claims 6, 26, 42, and 55 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Bardy* '414 as applied to claims 1, 21, 37, and 50 and further in view of *Brockway*. Claims 7, 27, 43, and 56 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Bardy* '376 as applied to claims 1, 21, 37, and 50 and further in view of U.S. Patent No. 5,814,079 to *Kieval et al.* (hereinafter "*Kieval*"). Claims 7, 27, 43, and 56 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Bardy* '414 as applied to claims 1, 21, 37, and 50 and further in view of *Kieval*. Claims 17-18 and 31-32 stand rejected under 35 U.S.C. §103(a) as being obvious over *Bardy* '376 as applied to claims 1 and 21, and further in view of U.S. Publication No. 2004/0215258 by *Lovett et al.* (hereinafter "*Lovett*").

The Applicant's dependent claims 17 and 31 each recite same variation of wherein the asystole prevention therapy comprises delivery of pacing pulses at a rate lower than a pacing rate associated with the bradycardia therapy.

In addressing the § 103(a) rejection of dependent claims 17 and 31, the Office Action identifies a "sub-threshold stimulation therapy" that "effect[s] maximal cardiac relaxation and suppress[es] aberrant electrical activity," as disclosed by *Kieval*. (Page 13). The Applicant respectfully submits that *Kieval*'s sub-threshold maximal cardiac relaxation and aberrant electrical activity suppression therapy is not a pacing therapy, but rather is a conditioning therapy for subsequent high voltage shock fibrillation therapy. (See Fig. 7). Moreover, it is doubtful that *Kieval*'s identified conditioning therapy could be an systole prevention therapy for at least the reason that the conditioning therapy does not "elicit a depolarization of myocardial cells of the heart." (Col. 5, Lines 16-18). As such, *Bardy* '414 does not teach or suggest all limitations of dependent claims 17 or 31, even in combination with *Kieval*.

Each of claims 6, 7, 17, 18, 26, 27, 31, 32, 42, 43, 55, and 56 depend from one of independent claims 1, 21, 37, and 50, respectively. Independent claims 1, 21, 37, and 50 are not obvious for at least the reason that the cited references fail to teach or suggest each and every limitation recited in each claim. Furthermore, while the Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 21, 37, and 50. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent claims 6, 7, 17, 18, 26, 27, 31, 32, 42, 43, 55, and 56 are not made obvious by *Bardy* '414 nor *Bardy* '376, even in combination with *Brockway*, *Kieval*, and *Lovett*.

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 6, 7, 17, 18, 26, 27, 31, 32, 42, 43, 55, and 56 and notification that these claims are in condition for allowance.

For at least these reasons, the Applicant respectfully submits that the rejection of claims 6, 7, 17, 18, 26, 27, 31, 32, 42, 43, 55, and 56 as being made obvious by *Bardy* '414 or *Bardy* '376, in combination with *Brockway*, *Kieval*, and *Lovett*, is not sustainable.

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in the Applicant's pending. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.611PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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